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NOV 30 2006

Application No. 10/602,190

Amendment and Response to Office Action

**REMARKS/ARGUMENTS**

*Status of the Claims*

Claims 1-7 are currently pending and claims 1, 3-4 and 7 have been amended correct typographical errors and to more particularly recite and distinctly claim the invention. No new matter has been added by way of the amendments.

*Claim Objections*

Claim 7 was objected to as allegedly failing to claim multiple dependency in the alternative. Claim 7 has been amended to clarify that the claim depends from "any one of" the referenced antecedent claims, making it clear that multiple dependency being claimed in the alternative. Claim 7 also has been amended to read more clearly as a therapeutic method claim. The amendment is believed to render moot the objection to claim 7. Accordingly, Applicants request withdrawal of the objection.

*Rejection under Section 112*

Claims 1-6 were rejected under 35 U.S.C. § 112 as allegedly indefinite in view of spelling errors, recitation of the phrase "other excipients if necessary," and elements that allegedly lack antecedent basis. Claims 1, 4 and 6 have been amended to correct the spelling errors, the phrase "other excipients if necessary" has been deleted from claims 1 and 6, and the dependency of claims 3, 4 and 6 has been amended to depend from claim 2, which provides antecedent basis for ketorolac tromethamine and tramadol hydrochloride. The amendments are believed to render moot the indefiniteness rejection. Accordingly, Applicants request withdrawal of this rejection.

*Rejections under Section 103*

Claims 1-6 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Raffa (EP 0546676) and Mauskop (U.S. 5,914,129) in view of Saslawski (U.S. 6,372,255) and the Physicians' Desk Reference. Applicants traverse.

Raffa discloses combining tramadol with NSAIDs in certain ratios. Although Raffa discloses a laundry list of potential NSAIDs, and exemplifies the combination of tramadol and ibuprofen, specifically, Raffa does not teach or suggest combining a non-steroidal anti-inflammatory and an opiate analgesic with colloidal silicate dioxide, sodium glycolate,

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lactose, microcrystalline cellulose, and magnesium stearate, as recited in claim 1. Further, there is no teaching in Raffa to combine tramadol with ketorolac, e.g., as recited in claim 2.

Mauskop discloses compositions for the treatment of migraines, which compositions include an opiate and an NSAID in combination with a stimulant and a magnesium salt. Optionally, the Mauskop composition may contain an effervescent agent. The preferred NSAID of Mauskop is ibuprofen or acetaminophen. Mauskop does not teach or suggest combining a non-steroidal anti-inflammatory and an opiate analgesic with colloidal silicate dioxide, sodium glycolate, lactose, microcrystalline cellulose, and magnesium stearate, as recited in claim 1. Further, Mauskop does not teach or suggest combining tramadol with ketorolac, e.g., as recited in claim 2.

Saslawski was cited as exemplary of excipients typically included in oral compositions, and the PDR was cited as disclosing the salt forms of tramadol and ketorolac. However, neither of these references teaches or suggests combining a non-steroidal anti-inflammatory and an opiate analgesic with colloidal silicate dioxide, sodium glycolate, lactose, microcrystalline cellulose, and magnesium stearate, specifically, as recited in claim 1. Further, Mauskop does not teach or suggest combining tramadol with ketorolac, e.g., as recited in claim 2.

The cited references teach do not teach or suggest a composition containing the particular combination of ingredients recited in the claims. At best, there are large lists from which to choose any opiate and any NSAID. There is no particular teaching of the claimed combination. As such, the cited references do not render obvious the claimed invention. Accordingly, Applicants request withdrawal of the obviousness rejection.

#### *Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

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Respectfully submitted,

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